

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA**

H. LUNDBECK A/S
Plaintiff,

V.

HON. KATHI VIDAL in her official role as)
 UNDER SECRETARY OF COMMERCE FOR)
 INTELLECTUAL PROPERTY AND)
 DIRECTOR OF THE UNITED STATES)
 PATENT AND TRADEMARK OFFICE)
 Defendant)

Civil Action No. 1:23-cv-01105

Assigned to:

Hon. Patricia Tolliver Giles, Judge

**PLAINTIFF H. LUNDBECK A/S'S COMBINED OPPOSITION TO DEFENDANT'S
CROSS MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF ITS
MOTION FOR SUMMARY JUDGMENT**

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Pursuant to Federal Rule of Civil Procedure 56, E.D. Va. Local Civil Rules 7 and 56, and this Court’s February 20, 2024 Order (Dkt. 39), Plaintiff H. Lundbeck A/S (“Lundbeck”) respectfully submits the following memorandum of law in support of its motion for summary judgment (Dkt. 28) and in opposition to Defendant Kathi Vidal’s motion for summary judgment (Dkt. 34) in the above-captioned action.

INTRODUCTION

The PTO’s summary judgment motion fails to engage with the “plain, clear, and conclusive” language of 35 U.S.C. § 154(b)(2)(C)(i), which forbids the PTO from reducing a patent’s term in excess of the “period equal to the period of time during which [an] applicant failed to engage in reasonable efforts to conclude prosecution of [its] application.” *Supernus Pharms., Inc. v. Iancu*, 913 F.3d 1351, 1358 (Fed. Cir. 2019). No regulation, let alone a non-binding public announcement contained in the MPEP that was neither cited nor relied upon during prosecution of the patent application at issue, can grant authority that *Congress* did not give. The PTO does not grapple with the plain language of Section 154(b)(2)(C)(i) because doing so would reveal that its decision to strip Lundbeck of patent term was *ultra vires*.

As detailed in Lundbeck’s Opening Brief (Dkt. 29), the PTO simply did not process Lundbeck’s patent application within 14 months of filing, which resulted in 134 days of undisputed A Delay. Rather than adjust the term of Lundbeck’s patent, as Congress intended, the PTO attempts to shift the blame for its delay by pointing to a purported formatting defect (shading in the headers of two tables that did not render the text illegible) that was not identified within eight months of filing and, thus, could not have been corrected in the same period.

The PTO contends that 37 C.F.R. § 1.704(c)(13) grants it the authority to deduct patent term even though it did not issue a formalities notice identifying the purported formatting defect until long after the eight-month period set forth in Rule 1.704(c)(13). This deduction was

improper because (1) the PTO did not give notice of the purported shading defect until 10 months after filing and (2) Lundbeck removed the shading within three months of the PTO's notice. Perhaps recognizing that not one of the regulations actually cited and relied upon in the Administrative Record says *anything* about shading, the PTO now attempts to pivot to a section of the MPEP that (1) it never cited or relied on when examining Lundbeck's application, (2) does not have the force of law, and (3) *also* does not ban shading in patent applications. This *post hoc* rationalization cannot save the PTO's *ultra vires* interpretation of 35 U.S.C. § 154(b)(2)(C)(i).

The plain language of Section 154(b) only allows the PTO to deduct patent term for the period of time that an applicant fails to take reasonable efforts to conclude prosecution, and not a day more. The PTO's efforts to distract this Court from the only real issues here—whether the PTO's interpretation of 35 U.S.C. § 154(b)(2)(C)(i) contradicts the statute's plain language and whether its application in this case is arbitrary and capricious—must fail. The PTO's inconsistent application of its regulations have led it to reduce patent term where the plain language of 35 U.S.C. § 154(b)(2)(C)(i) says it cannot. The Court should grant summary judgment to Lundbeck, deny the PTO summary judgment, and restore Lundbeck's patent term.

BACKGROUND AND ADDITIONAL UNDISPUTED FACTS

I. SECTION 154(B)(1)(A) AND THE 14-MONTH TIMELINE CONGRESS SET FOR PROCESSING A PATENT APPLICATION

This case concerns U.S. Application No. 16/349,047 (the “047 application”), which was a national stage application for a patent pursuant to 35 U.S.C. § 371. Under Section 371(c), a national stage application commences once an applicant (1) files the national fee; (2) provides a copy of the international application; (3) provides amendments to the international application, if not already provided to the PTO by the International Bureau; (4) provides an oath or declaration of the inventor; and (5) provides a translation into English of any annexes to the international

preliminary examination report. The parties agree that Lundbeck completed these steps on May 10, 2019 and that, pursuant to 35 U.S.C. § 371(f), the national stage application officially commenced on May 16, 2019. *See* SUF ¶ 2.¹

The PTO contends that, notwithstanding its agreement that Lundbeck submitted a copy of the international application in accordance with 35 U.S.C. § 371(c) on May 10, 2019, that application was not in condition for examination in accordance with PTO regulations because of shading in the headers of two tables on pages 80 through 84 and 139 of the specification. *See, e.g.*, SUF ¶ 7. The parties agree that the PTO did not inform Lundbeck of this fact until March 11, 2020, more than 10 months after Lundbeck filed its national stage application. *See* SUF ¶¶ 6–7. The PTO contends that it had no obligation to process Lundbeck’s application on any particular schedule or to issue a formalities notice within any particular time frame. *See* Def.’s Resp. Br. at 2–3 (Dkt. 35) (“The PTO is under no obligation to provide such a notice within a particular time period.”).² Such a position ignores 35 U.S.C. § 154(b)(1)(A).

Section 154(b)(1)(A) obliges the PTO to either issue a notice of allowance or office action within 14 months of the filing of an application, including the national stage of an international application under 35 U.S.C. § 371. *See* Pl.’s Opening Br. at 2 (Dkt. 29). Whenever the PTO fails to do so, Congress dictated that “the term of the patent shall be extended 1 day for

¹ As explained in the Complaint, Lundbeck obtained all rights to the ’047 application, which was originally filed by Abide Therapeutics, Inc (“Abide”). *See* SUF ¶ 1. Although Abide is the original applicant of the ’047 application, for convenience, all references to the applicant for the ’047 application will refer to “Lundbeck.”

² *See also* Def.’s Resp. Br. at 11, ¶ 6 (Dkt. 35) (“Undisputed to the extent that there is no implication that the USPTO had an obligation to send Plaintiff notice about the gray shading in the tables.”); *id.* at 25 n.10 (“There is no statutory or regulatory obligation for the USPTO to send a Formalities Letter at a time certain. Congress only instructed the agency to act within a certain period of time for certain types of agency actions, such as Office actions under 35 U.S.C. § 132. *See* 35 U.S.C. § 154(b)(1)(A)–(B).”).

each day” the PTO fails to act after 14 months. 35 U.S.C. § 154(b)(1)(A).

Contrary to the PTO’s suggestion, Congress did not set this 14-month deadline from the date the PTO considers an application to be in condition for examination. *Cf.* Def.’s Resp. Br. at 25 n.10 (Dkt. 35) (suggesting 35 U.S.C. § 154(b)(1)(A) only concerns the time to issue an office action). Rather, the plain language of 35 U.S.C. § 154(b)(1)(A) starts the clock at the moment “an application was filed under section 111(a) or the date of commencement of the national stage under section 371 in an international application,” and stops it only after a notice of allowance or notification under section 132 is provided. *Id.* at (b)(1)(A)(i) & (ii). Processing a patent application (and entering a formalities notice as appropriate) is a necessary, intermediate step to the ultimate goal of either allowing or issuing an office action in response to an application. Congress concluded this entire process should take no longer than 14 months. *See id.*

II. THE MANUAL OF PATENT EXAMINING PROCEDURE

As stated in its Foreword, the Manual of Patent Examining Procedure (“MPEP”) is a “reference work” meant to capture “the practices and procedures relative to the prosecution of patent applications and other proceedings before the USPTO.” MPEP (9th ed. Rev. Aug. 2017).³ The MPEP “does not have the force of law or the force of the rules in Title 37 of the Code of Federal Regulations.” *Id.* It does not bind any reviewing court. *See Natural Alternatives Int’l, Inc. v. Iancu*, 904 F.3d 1375, 1382 (Fed. Cir. 2018). And it may not exceed the statutory authority provided by Congress for the PTO to promulgate regulations. *See In re Recreative Techs. Corp.*, 83 F.3d 1394, 1397–98 (Fed. Cir. 1996).

Because the MPEP does not have the “force of the rules in Title 37 of the Code of

³ For the remainder of this brief, unless otherwise stated, any reference to MPEP refers to the August 2017 version of the MPEP cited in the PTO’s Responsive Brief. *See* Dkt. 35.

Federal Regulations,” it is not entitled to *Chevron*⁴ or *Auer*⁵ deference. *Cf. Aqua Prods. Inc. v. Matal*, 872 F.3d 1290, 1318 (Fed. Cir. 2017) (plurality opinion) (“‘interpretive’ nonbinding” discussion of an issue not entitled to *Chevron* or *Auer* deference) (citing *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000), for the proposition that “interpretations contained in [agency] policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference”). Indeed, even as to formal agency rules or decisions, the era of deference to agencies may end after the Supreme Court’s forthcoming decisions in *Loper Bright Enters. v. Raimondo*, No. 22-451 (U.S. oral argument Jan. 17, 2024), and *Relentless, Inc. v. Dep’t of Commerce*, No. 22-1219 (U.S. oral argument Jan. 17, 2024). In any event, the PTO expressly disavowed entitlement to *Chevron* deference, Def.’s Resp. Br. at 15 n.7 (Dkt. 35) (“Because this case turns on the language of 35 U.S.C. § 154(b)(2)(C)(i), the USPTO does not argue that its conduct is entitled to deference under *Chevron* ...”), and made no argument with respect to *Auer* deference, *see id.*

III. ADDITIONAL STATEMENT OF UNDISPUTED FACTS

Consistent with E.D. Va. Local Civil Rule 56(B), Lundbeck provides the following additional undisputed facts in light of the facts recited in the PTO’s Responsive Brief (Dkt. 35):

45. MPEP § 608.01(I) says, in relevant part:

Legibility includes ability to be photocopied and scanned so that suitable reprints can be made and paper can be electronically reproduced by use of digital imaging and optical character recognition. This requires a high contrast, with black lines and a white background. Gray lines and/or a gray background sharply reduce photo reproduction quality.

46. The March 11, 2020 Formalities Letter did not cite or rely on MPEP § 608.01(I).

See AR469–70. Rather, the only portion of the MPEP cited in the March 11, 2020 Formalities

⁴ *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

⁵ *Auer v. Robbins*, 519 U.S. 452 (1997).

Letter was MPEP § 608.01(q), which does not discuss shading or a “gray” background. *Id.*

47. The July 13, 2021 Issue Notification also did not cite or rely on MPEP § 608.01(I). AR1232.

48. The February 7, 2022 Decision on Petition also did not cite or rely on MPEP § 608.01(I). *See* AR1242–50.

49. The April 13, 2022 Redetermination of Patent Term Adjustment also did not cite or rely on MPEP § 608.01(I). *See* AR1256–62. Rather, the only portion of the MPEP cited in the April 13, 2022 Redetermination of Patent Term Adjustment was MPEP § 608.01(q), which does not discuss shading or a “gray” background. AR1261.

50. The February 24, 2023 Decision Denying Request for Redetermination of Patent Term Adjustment also did not cite or rely on MPEP § 608.01(I). AR1284–91. Rather, the only portion of the MPEP cited in the February 24, 2023 Decision Denying Request for Redetermination was MPEP § 608.01(q), which does not discuss shading or a “gray” background. AR1289.

51. Based on a search for the terms “MPEP” and “Manual of Patent Examining Procedure,” the only citations to the MPEP within the Administrative Record in this case are to the following sections: 302.08 (AR462, 1220); 325 (AR446, 1217); 503 (AR94, 268, 445, 449, 783, 1147, 1154, 1190, 1207, 1228, 1240, 1265); 506 (AR94, 268, 445, 449, 783, 1147, 1154, 1190, 1207, 1228, 1240, 1265); 605.01 (AR446, 1217); 608.01(q) (AR469–70, 1261, 1289); 609 (AR430–35, 801–05, 1140–41, 1148, 1166–67, 1183–85, 1193, 1201–03); 609(B) (AR437, 1150, 1195); 609.04(b) (AR436, 1149, 1166, 1194); 901.04 (AR430–31, 801–02, 1140, 1166, 1183–84, 1201–02); 1308 (AR1168, 1172, 1199); 1810 (AR94, 268, 445, 449, 783, 1147, 1154,

1190, 1207, 1228, 1240, 1265).⁶

52. The PTO neither cited nor relied on MPEP § 608.01(I) when making any determination in this case. *See* AR1–1291. Nor did the PTO point to a single instance in the Administrative Record where the PTO cited or relied on MPEP § 608.01(I). *See* Def.’s Resp. Br. (Dkt. 35).

53. The PTO neither cited nor relied on Customer Number Bar Code Labels and Papers with Shaded Portions Will No Longer Be Permitted in Correspondence for Patent Applications, 1274 Off. Gaz. Pat. & Trademark Office 105 (Sept. 16, 2003), *available at* <https://www.uspto.gov/web/offices/com/sol/og/2003/week37/patshad.htm>.⁷ *See* AR1–1291.

ARGUMENT

This dispute is the product of the PTO’s attempts to deflect the blame for its failure to process Lundbeck’s patent application within 14 months of filing, as required by the plain language of 35 U.S.C. § 154(b)(1)(A)(i). Because the PTO took over 18 months to issue an office action, Lundbeck was entitled to 134 days of A Delay. *See* SUF ¶ 23.

Instead of accepting blame for this delay, as Congress intended, the PTO has attempted to regulate its way out of it, first by blaming Lundbeck for purported legibility problems Lundbeck could not have known about in the first instance and second by charging additional delay for time taken to respond to a formalities notice, even where the response was provided in fewer than three months and within the period specified by the PTO’s notice. Perhaps recognizing that

⁶ Lundbeck relied on an electronic search of the Administrative Record in this case, which spans 1,291 pages. Although Lundbeck attempted to catch every instance, it is possible a citation was missed. In such case, any omission was inadvertent.

⁷ This statement is based on an electronic search for the terms “Customer Number Bar Code Labels and Papers with Shaded Portions” and “1274 Off. Gaz. Pat. & Trademark Office 105.” Moreover, the PTO did not point to any instance in the Administrative Record where the PTO cited or relied on this publication. *See* Def.’s Resp. Br. at 6–7 (Dkt. 35).

the Title 37 regulations actually cited in the Administrative Record do *not* support such actions, the PTO now invokes a section of the MPEP never before cited in prosecution of the '047 application: section 608.01(I). Even if properly considered (and it is not), this section cannot save the PTO's radical departure from the plain language of 35 U.S.C. § 154(b)(2)(C)(i), which allows the PTO to deduct *only* time in which an applicant fails to engage in reasonable efforts. For at least these reasons, summary judgment should be granted to Lundbeck.

I. THE PLAIN LANGUAGE AND STRUCTURE OF SECTION 154(B) CONTRADICT THE PTO'S DECISION.

The first question is “whether the statutory text forecloses the agency’s assertion of authority, or not.” *City of Arlington v. FCC*, 569 U.S. 290, 301 (2013). The PTO refuses to confront that question, ignoring the plain language of 35 U.S.C. § 154(b)(2)(C)(i), which says:

(b) Adjustment of patent term.—(2) Limitations.— (C) Reduction of period of adjustment.—(i) The period of adjustment of the term of the patent under paragraph (1) *shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.*

(emphasis added). The plain language of the statute is clear: the PTO can only reduce PTA for a period of time “equal to” the time during which an applicant failed to engage in reasonable efforts to prosecute its application. *Id.* Any rule or application of a rule promulgated by the PTO that results in a reduction of PTA that is greater than the period of time “equal to” the time during which an applicant failed to engage in reasonable efforts is invalid and exceeds the statutory authority granted to the PTO by Congress. *See Supernus Pharms.*, 913 F.3d at 1358.

The PTO's *only* argument that Lundbeck “failed to engage in reasonable efforts” relies on a section of the MPEP that the PTO never bothered citing at any point during prosecution of the '047 application, *see* SUF ¶ 52, and that does not have the binding force of law—neither as a statute nor as a regulation promulgated in Title 37, *see* MPEP Foreword. Even if this *post hoc*

rationalization were appropriate—and it is not, *see infra* at 24–27—no MPEP provision can supplant the plain language of 35 U.S.C. § 154(b)(2)(C)(i), which does not allow the PTO to deduct a single day longer than the time an applicant fails to engage in “reasonable efforts.”

A. The Plain Language of 35 U.S.C. § 154(b)(2)(C)(i) Contradicts The PTO’s Decision.

1. The Plain Language of 35 U.S.C. § 154(b)(1)(A)(i) Contradicts The PTO’s Justification For Its Failure To Issue A Formalities Notice Before The Eight-Month January 17, 2020 Deadline.

The PTO argues that it has no obligation to process an application within any period of time. *See, e.g.*, Def.’s Resp. Br. at 2–3 (Dkt. 35). The PTO is wrong. By providing for A Delay, Congress evidenced a clear intention for the PTO to both process and begin examination of a pending patent application within 14 months.

The parties agree that 35 U.S.C. § 154(b)(1)(A) requires either a notice of allowance or first office action to be provided within 14 months of the commencement of a national stage of an international application. *See Mohsenzadeh v. Lee*, 790 F.3d 1377, 1378 (Fed. Cir. 2015); *see also Pfizer, Inc. v. Lee*, 811 F.3d 466, 469 (Fed. Cir. 2016). This was not done here. *See* SUF ¶¶ 20, 23. As a result, the parties agree that the PTO accrued 134 days of A Delay under 35 U.S.C. § 154(b)(1)(A). *See* SUF ¶ 23. This A Delay was the product of *both* the PTO’s failure to process Lundbeck’s application in a timely manner *and* substantively examine it for purposes of issuing a timely office action or notice of allowance.

It took the PTO 300 days (nearly 10 months) to process Lundbeck’s application and issue a formalities notice. *See* SUF ¶¶ 2, 6–7; *see also infra*, Figure 1. On November 27, 2020, eight months and 16 days after the formalities notice, the PTO issued an office action, as shown in Figure 2 below. *See* SUF ¶¶ 7, 15. It took a little longer than 18 months for the PTO to both process Lundbeck’s application and issue its first office action. *See infra*, Figure 1 & Figure 2.

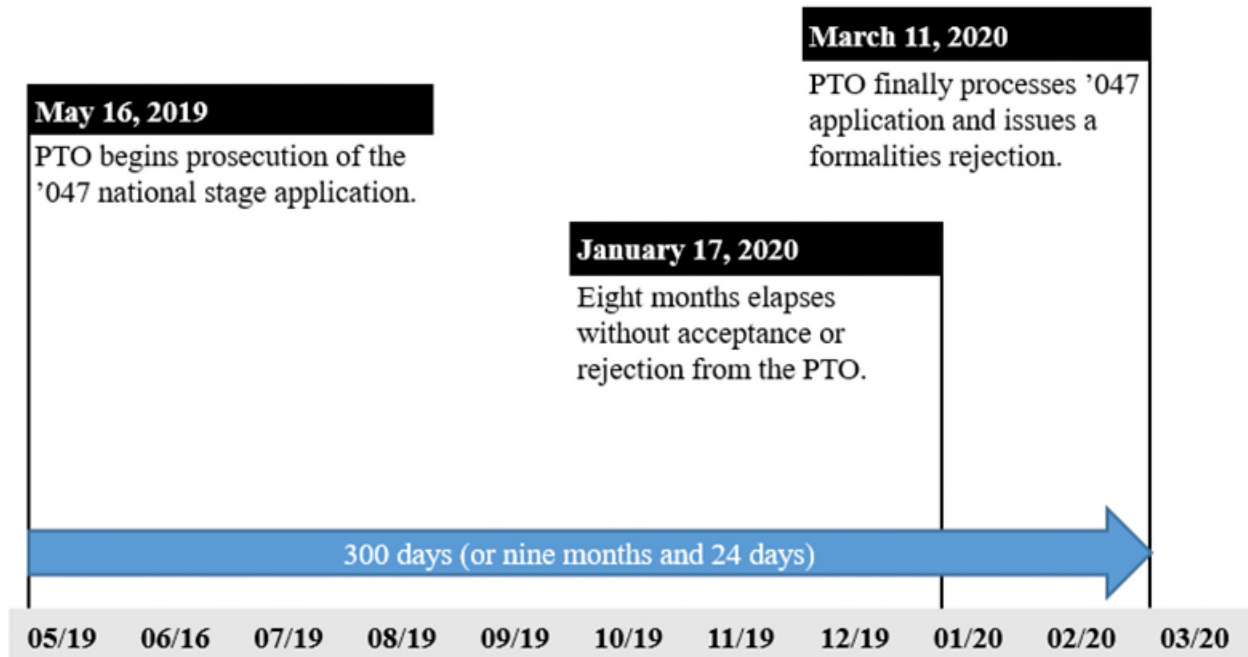


Figure 1. Time for the PTO To Issue A Formalities Notice

The PTO acts as though the only “back and forth” between an applicant and the PTO occurs during the substantive examination period. *Cf.* Def.’s Resp. Br. at 7 (Dkt. 35). But this is only part of the story. The PTO also engages in a *pre-examination* “back and forth” process with applicants, and the Section 154(b)(1)(A)(i) deadline is concerned with those interactions as well.

Congress set out a 14-month period that runs from the date of *filing*—and thus includes time for the PTO to both process an application and examine it—to either issue an office action or notice of allowance. 35 U.S.C. § 154(b)(1)(A). Congress could have easily passed a statute that said the PTO’s A Delay clock started once an application was “in condition for examination.” Instead, Congress decided the clock should start when the application was *filed*, even if that application contained some formatting or other deficiencies, and gave the PTO 14 months to both notify applicants of any formatting defects *and* issue either a notice of allowance or first office action. 35 U.S.C. § 154(b)(1)(A)(i); *see also* Changes To Implement the Patent Law Treaty, 78 Fed. Reg. 62368, 2013 WL 5687792 (Oct. 21, 2013) (hereinafter, “Patent Law

Treaty Changes”) (noting that once the specification and claims are filed, the PTO could “conduct a formalities review and issue a notice (if necessary) requiring the applicant to complete the application and correct any application informalities no later than one to two months from the filing of an application” and, therefore, within the 14-month period).

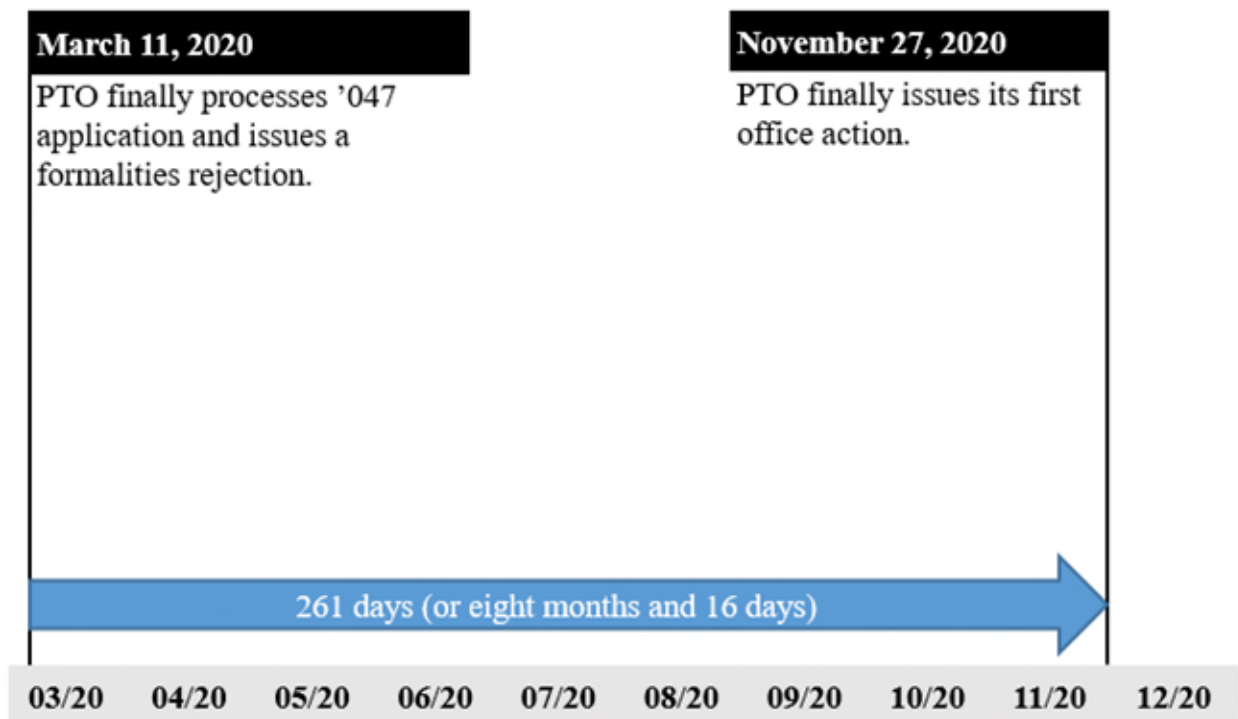


Figure 2. Time for the PTO To Issue An Office Action

As applied here, the PTO did not begin examination of the '047 application until June 5, 2020, when Lundbeck filed a version of the specification without shading in the tables. *See* SUF ¶ 13. The PTO issued its first office action approximately six months later, on November 27, 2020. *See* SUF ¶ 15. Accordingly, it took the PTO only five months and 22 days to substantively examine the “corrected” application that Lundbeck filed on June 5, 2020. *See id.* In the hypothetical world where the 14-month clock applied only to the time devoted to substantive examination of an application, there would have been no A Delay in this case, as

illustrated in Figure 3.

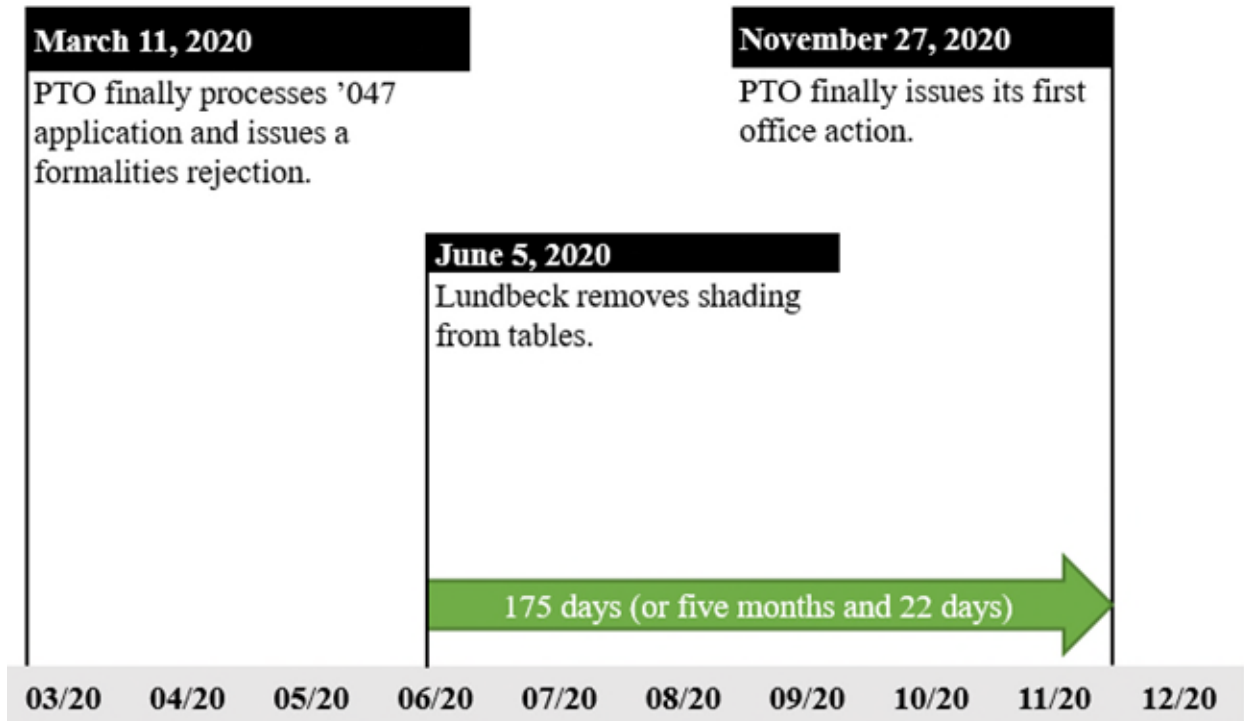


Figure 3. Time for the PTO To Process The “Corrected” Application

But that is not the world Congress chose. Instead, Congress decided that the 14-month clock starts the moment an application is *filed*, which means that it necessarily applies to both pre-examination and substantive examination of an application. *See* 35 U.S.C. § 154(b)(1)(A). Hence, as applied here, all parties agree that the PTO correctly calculated the amount of A Delay in this case to be 134 days, which *includes* the 18 months it took to both complete pre-examination and begin substantive examination of the application, as illustrated in Figure 4 below. *See* SUF ¶ 24. The bulk of this delay occurred during the pre-examination period, where the PTO deviated from the estimated “five months” the PTO claimed was needed to complete the pre-examination “formalities review” process when promulgating Rule 1.704(c)(13). Patent Law Treaty Changes, 78 Fed. Reg. at 62384; *see also id.* at 62384–85 (further explaining that the purpose of Rule 1.704(c)(13) was to protect against applicants who might attempt to game the system and cause A Delay by not submitting a specification *at all*).

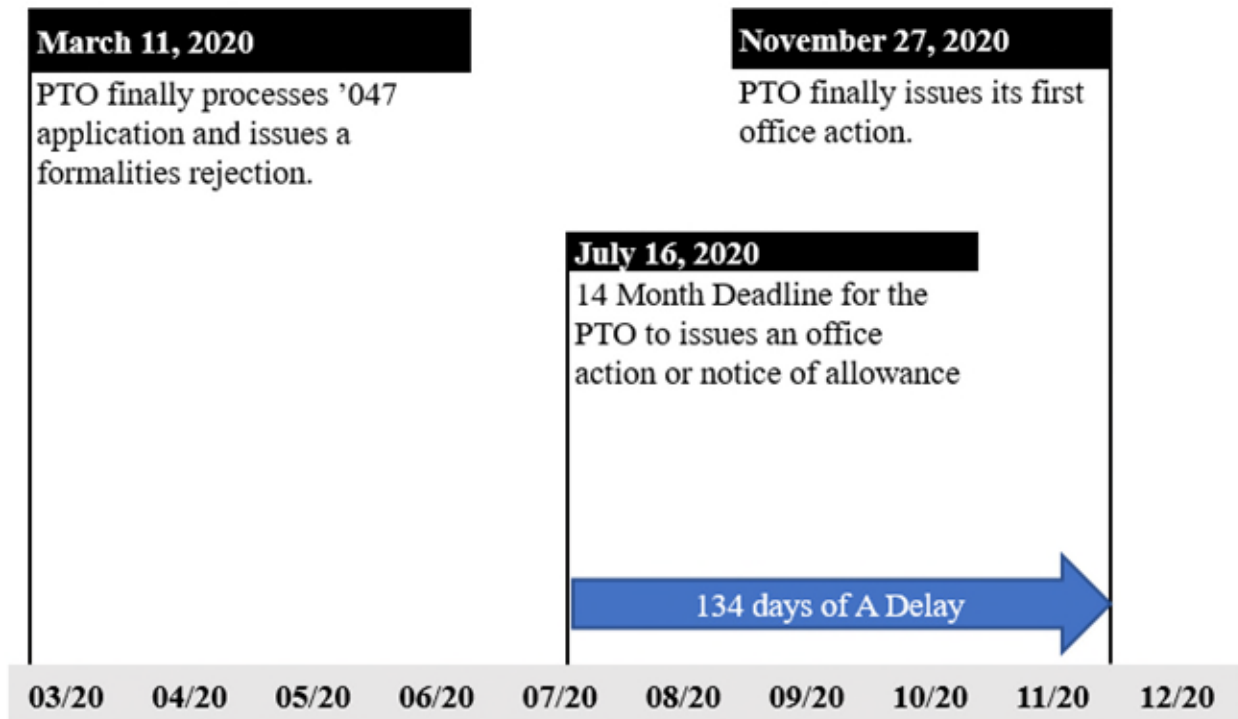


Figure 4. 134 Days of A Delay under 35 U.S.C. § 154(b)(1)(A)

Put simply, it is not true that Congress expressed no concern about the time it took the PTO to process an application and iron out any formalities deficiencies in pre-examination before beginning substantive examination of an application. Congress evidenced its concern through the language of 35 U.S.C. § 154(b)(1)(A). This case arises because of the PTO's attempts to *escape* the remedy Congress crafted to protect an applicant's patent term against delays by the PTO during both the pre-examination and substantive examination periods.

2. The PTO deprived Lundbeck of the ability to act by withholding vital information regarding a purported legibility issue until months after the eight-month deadline under Rule 1.704(c)(13).

The Federal Circuit recently held that "the USPTO may not count as applicant delay a period of time during which there was no action that the applicant could take to conclude prosecution of the patent." *Supernus*, 913 F.3d at 1358. The PTO acknowledges this holding. *See* Def.'s Resp. Br. at 15 (Dkt. 35). Nevertheless, the PTO argues that, in this case, Lundbeck

could have and should have removed the shading earlier because (1) MPEP § 608.01(I) “exist[ed],” (2) Lundbeck could (and should) have known about it, and (3) the public announcement contained therein somehow operated as a complete ban on all shading. *See id.* at 19–22. Not one of these arguments holds water. *See infra* at 24–27. More importantly, they are all distractions from the real issue: 37 C.F.R. § 1.704(c)(13) may not be applied (or interpreted through public announcements like the MPEP) in a manner that contradicts the plain language of 35 U.S.C. § 154(b)(2)(C)(i). *See* Pl.’s Opening Br. at 17–24 (Dkt. 29).

Subsection (C)(i) of § 154(b)(2)(C)(i) sets out a straightforward framework for PTA reductions: PTA “shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution.” 35 U.S.C. § 154(b)(2)(C)(i). Congress did not set out a strict liability regime. Instead, Congress decided that patent term should only be deducted when applicants fail to behave “reasonab[ly].” *Id.* Lundbeck filed a wholly legible application and waited for the PTO to process it. *See* SUF ¶¶ 2–6. The only regulatory requirements were that the text be sufficiently legible. *See* 37 C.F.R. § 1.52(a)(1)(v). It was. *See* SUF ¶ 4. Thus, Lundbeck did not fail to engage in reasonable efforts. Only the PTO could have told Lundbeck that its reproduction equipment would somehow render Lundbeck’s legible text illegible. The PTO waited 10 months to provide that information. Any “delay here was indisputably attributable to the PTO.” *Ariad Pharms., Inc. v. Matal*, 283 F. Supp. 3d 503, 510 (E.D. Va. 2018). The PTO’s decision to use § 1.704(c)(13) to blame Lundbeck for its own failures “is not faithful to the plain meaning and purpose of the statute.” *Ariad Pharms.*, 283 F. Supp. 3d at 512; *see also Gilead Scis., Inc. v. Lee*, 778 F.3d 1341, 1349 (Fed. Cir. 2015) (citing H.R. Rep. No. 106-287, at 50) (noting the legislative history of the PTA statute “emphasized that the statute was intended to penalize ‘only those who

purposely manipulate the system *to delay the issuance of their patents*”).

The parties do not *really* dispute that the two tables on pages 80 through 84 and 139 of the specification were readily legible when filed. *See* SUF ¶¶ 3–4. The PTO does not point to any finding of illegibility in the Administrative Record. *See* SUF ¶¶ 3–4, 8. Nor does the PTO point to any finding that Lundbeck *should have* known a PTO reproduction process would render its tables illegible. *See* SUF ¶¶ 5, 9. *But see* Def.’s Resp. Br. at 20 n.9 (Dkt. 35) (improperly asking the Court to infer reasoning not included in the Administrative Record). No reasonable factfinder could conclude otherwise. Lundbeck can hardly be faulted for not fixing an issue for which it had no notice. *See* Pl.’s Opening Br. at 18–19 (Dkt. 29).

The PTO’s *only* response is the MPEP § 608.01(I)’s general statement that gray backgrounds *reduce* legibility. *See* Def.’s Resp. Br. at 11 (Dkt. 35) (SUF ¶ 4). Even if the PTO had cited or relied on MPEP § 608.01(I) during prosecution—and it did not (*see* SUF ¶ 52)—such reliance would be unavailing. Section 608.01(I) says that gray backgrounds reduce legibility. It does not say they are forbidden. Lundbeck reasonably believed its tables were legible. The PTO does not respond to the fact that the only way for Lundbeck to know whether the PTO’s reproduction equipment would render the text in the shaded tables illegible was for the PTO to share that information. *See* SUF ¶¶ 5, 8–9. Instead, the PTO withheld this information until 10 months after filing. SUF ¶¶ 6–7, 31. The plain language of 35 U.S.C. § 154(b)(2)(C)(i) forbids any regulation (or nonbinding guidance like the MPEP) from blaming *Lundbeck* for the *PTO’s* delay. *See Wyeth v. Kappos*, 591 F.3d 1364, 1370 (Fed. Cir. 2010) (“The problem with the PTO’s interpretation is that it considers the application *delayed* ... during the period *before it has delayed*.”); *see also* Patent Law Treaty Changes, 78 Fed. Reg. at 62384 (stating the pre-examination process should be completed within five months).

The PTO's reliance on 35 U.S.C. § 154(b)(2)(C)(iii) offers no escape from this conclusion. That provision provides authority for the Director to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." 35 U.S.C. § 154(b)(2)(C)(iii). It must be interpreted, and applied consistently with, subsections (C)(i) and (C)(ii). *See TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is 'a cardinal principle of statutory construction' that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." (citations omitted)); *see also Timex V.I., Inc. v. United States*, 157 F.3d 879, 882 (Fed. Cir. 1998) (Congressional intent is derived in part from "the statute's structure, canons of statutory construction, and legislative history"); *Gilead*, 778 F.3d at 1348 (same). Subsection (C)(iii) does *not* provide *carte blanche* authority for the PTO to blame applicants for the *PTO's* delay.

The relevant regulations at issue here include 37 C.F.R. § 1.704(c)(13), which says:

Failure to provide an application in condition for examination as defined in paragraph (f) of this section *within eight months* from either the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is eight months from either the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application and ending on the date the application is in condition for examination as defined in paragraph (f) of this section[.]

(emphasis added). Rule 1.704(f) says, in relevant part: "An application filed under 35 U.S.C. 111(a) is in condition for examination when it includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has papers in compliance with § 1.52" 37 C.F.R. § 1.704(f). Rule 1.52 requires all papers to be:

Presented in a form having sufficient clarity and contrast between the paper and

the writing thereon to permit the direct reproduction of readily legible copies in any number by use of photographic, electrostatic, photo-offset, and microfilming processes and electronic capture by use of digital imaging and optical character recognition.

37 C.F.R. § 1.52(a)(1)(v). The purpose of Rule 1.704(c)(13) was to address intentional applicant delay where no specification was included in an initial filing. *See* Patent Law Treaty Changes, 78 Fed. Reg. at 62384–85. It was not meant to be a trap for minor formalities defects. *See id.*

The PTO’s application of the “within eight months” language of Rule 1.704(c)(13) blames the applicant for any issues with the application, even if input from the PTO is required to *detect* such issues. Pl.’s Opening Br. at 19 (Dkt. 29). This divorces Rule 1.704(c)(13) from applicant conduct, which 35 U.S.C. § 154(b)(2)(C)(i) does not allow. *See Gilead*, 778 F.3d at 1348 (“Congress’s primary intent was to penalize applicant *conduct*”); *see also Supernus*, 913 F.3d at 1358–60. Any “period of adjustment” must be “equal to” the “period of time” “during which” an “applicant failed to engage in reasonable efforts.” 35 U.S.C. § 154(b)(2)(C)(i).

The PTO does not address this argument *at all*. Instead, it pivots to the general statements provided in MPEP § 608.01(I), which it contends should have placed Lundbeck on notice that the shading in tables 80 through 84 and 139 *would* pose a legibility issue. But, as is discussed more fully below, *see infra* at 25–27, the MPEP is not a regulation prescribed in accordance with 35 U.S.C. § 154(b)(2)(C)(iii). Accordingly, the import of the MPEP is nothing more than a public announcement by the PTO without *any* authority.⁸ That public

⁸ The PTO’s reliance on a *dissenting* opinion to argue that Lundbeck had an obligation to consider MPEP § 608.01(I) not only flies in the face of the *MPEP*’s admission that it does *not* have the force of law or any regulation promulgated under Title 37, but it also directly contradicts the Federal Circuit’s *precedential* guidance on the subject. *Compare* Def.’s Resp. Br. at 20 (Dkt. 35) (citing Judge Prost’s dissenting opinion in *Leviton Mfg. Co. v. Universal Sec. Instr., Inc.*, 606 F.3d 1353, 1373 (Fed. Cir. 2010), with *Belkin Int’l, Inc. v. Kappos*, 696 F.3d 1379, 1384 (Fed. Cir. 2012) (stating that the MPEP does not “have the force of law” and is only entitled judicial notice when it does not contradict official interpretations of statutes and regulations), and *Natural Alternatives Int’l, Inc.*, 904 F.3d 1375, 1382 (same).

announcement says gray shading *reduces* legibility, not *destroys* it. Even if this public announcement can somehow be imported into Rule 1.704(c)(13), and it *cannot*, this does not amount to a statement that all gray shading *necessarily* renders any text illegible.

As a preliminary matter, the plain language of MPEP § 608.01(I) does not ban all shading. That is, MPEP § 608.01(I) says:

Legibility includes ability to be photocopied and scanned so that suitable reprints can be made and paper can be electronically reproduced by use of digital imaging and optical character recognition. This requires a high contrast, with black lines and a white background. Gray lines and/or a gray background sharply reduce photo reproduction quality.

Indeed, § 608.01(I) discusses only one aspect of legibility: “...*the ability to be photocopied and scanned* so that suitable reprints can be made....”). MPEP § 608.01(I) (emphasis added). An application can certainly be “photocopied and scanned” with a gray background and black text. “[S]ufficient clarity and contrast” are also achievable with a gray background and black text. 37 C.F.R. § 1.52(a)(1)(v). While “[g]ray lines and/or gray backgrounds” may reduce photo reproduction quality, this is not tautologically the case. MPEP § 608.01(I).

The phrase “shades of gray” is a colloquialism for a reason. Some shades would make a table less legible when photocopied; others would have no meaningful impact on the table’s legibility. Consider, for example, the 12 shades of gray in Table 1 below.

Table 1. Exemplary Chart Showing Legibility of 12 Shades of Gray
Example 1 (Hex Color Code: F8F8F8)
Example 2 (Hex Color Code: EAEAEA)
Example 3 (Hex Color Code: DDDDDD)
Example 4 (Hex Color Code: C0C0C0)
Example 5 (Hex Color Code: B2B2B2)
Example 6 (Hex Color Code: 969696)
Example 7 (Hex Color Code: 808080)
Example 8 (Hex Color Code: 777777)

Table 1. Exemplary Chart Showing Legibility of 12 Shades of Gray
Example 9 (Hex Color Code: 5F5F5F)
Example 10 (Hex Color Code: 4D4D4D)
Example 11 (Hex Color Code: 333333)
Example 12 (Hex Color Code: 292929)

To say that the gray shading in Examples 1 through 6 *necessarily* renders any text illegible would be unreasonable and unsupported by substantial evidence. That the shading in Examples 7 through 12 *could* pose legibility issues does not mean *all* gray shading renders text illegible, which is precisely why MPEP § 608.01(I) does not even purport to forbid all shading. *See* SUF ¶ 45. Rules 1.704(c)(13), 1.704(f), and 1.52(a)(1)(v) also do not include any such shading ban.⁹ *See* SUF ¶ 9.

As applicable here, the shade of gray used in Lundbeck's tables in no way caused legibility issues. The screenshots below, which themselves are reproductions of reproductions, illustrate that Lundbeck's tables were sufficiently legible, as required by Rule 1.52(a)(1)(v).

Chemical Synthesis Example	Structure	Name
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Figure 5. Shaded Table from Page 80 of the Specification (AR363)

⁹ Indeed, the *current* version of the MPEP does not ban gray shading either: Legibility includes ability to be photocopied and scanned so that suitable reprints can be made and paper can be electronically reproduced by use of digital imaging and optical character recognition. This requires a high contrast, with black lines and a white background. Gray lines and/or a gray background sharply reduce photo reproduction quality. In order to enhance readability of electronic submissions, the USPTO *strongly recommends* use of a black colored font for text on a white background. MPEP § 608.01(I) (9th ed. Rev. Jul. 2022) (emphasis added).

Chemical Synthesis Example	Structure	Name
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Figure 6. Shaded Table from Page 81 of the Specification (AR364)

Chemical Synthesis Example	Structure	Name
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Figure 7. Shaded Table from Page 82 of the Specification (AR365)

Chemical Synthesis Example	Structure	Name
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Figure 8. Shaded Table from Page 83 of the Specification (AR366)

Chemical Synthesis Example	Structure	Name
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Figure 9. Shaded Table from Page 84 of the Specification (AR367)

Ex	MAGL IC ₅₀ (μM) (human)	MAGL % inh. 5 mg/kg (mouse)	Ex	MAGL IC ₅₀ (μM) (human)	MAGL % inh. 5 mg/kg (mouse)
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Figure 10. Shaded Table from Page 139 of the Specification (AR422).

Without information from the PTO, Lundbeck had no way of knowing the shades of gray used in its *specific* tables would cause legibility issues when reproduced by the PTO because the '047 application's shades of gray did not present any obvious legibility issues. *See supra* Figure 5–Figure 10. The PTO offers no argument to the contrary, relying solely on the public

announcement in MPEP § 608.01(I) that gray shading reduces legibility without any analysis as to the gray shading at issue *in this case*. See Def.’s Resp. Br. at 19-20 (Dkt. 35). This is because the PTO did not conduct any specific analysis of the gray shading at issue *here*, instead reciting Rule 1.704(c)(13) and 1.52(a)(1)(v), neither of which forbids shading of any kind. See SUF ¶ 9. The PTO’s decision to nonetheless reduce the patent term is *ultra vires*.

As discussed in Lundbeck’s Opening Brief, both the text and structure of 35 U.S.C. § 154(b)(2)(C) allow the PTO to reduce patent term only when an applicant is (1) on notice, (2) has an ability to engage with the PTO, and (3) fails to engage with the PTO to conclude prosecution. Pl.’s Opening Br. at 20 (Dkt. 29). Given the shades of gray chosen by Lundbeck, the only way for Lundbeck to know there was a potential legibility issue was for the PTO to provide that information. SUF ¶ 5. The PTO’s failure to do so until nearly 10 months after filing is not “applicant conduct” for which Lundbeck can be blamed under 35 U.S.C. § 154(b)(2)(C)(i). See *Gilead*, 778 F.3d at 1347; see also *Supernus*, 913 F.3d at 1359.

The PTO has no right to divorce Rule 1.704(c)(13) from the plain text of 35 U.S.C. § 154(b)(2)(C)(i). Pl.’s Opening Br. at 21 (Dkt. 29). The PTO has even fewer rights to reduce the patent term based on public announcements in the MPEP, which are *not* prescribed under 35 U.S.C. § 154(b)(2)(C)(iii). At a minimum, no patent term should have been deducted until the PTO notified Lundbeck of the legibility issue.

Supernus confirms, if not *demand*s, this outcome. See Pl.’s Opening Br. at 21–22 (Dkt. 29) (summarizing the facts of *Supernus*). The PTO argues that *Supernus* is somehow distinguished from this case because, in that case, “all parties agreed that there was nothing the applicant could have done to advance prosecution.” Def.’s Resp. Br. at 21 (Dkt. 35). Not quite. In briefing before the Federal Circuit, the PTO argued that *Supernus* could have availed itself of

the 30-day safe harbor provided by Section 1.704(d)(1), thereby avoiding any Applicant Delay. *See* Corrected Brief of Defendant at 4, *Supernus Pharms., Inc. v. Lee*, No. 17-1357 (Fed. Cir. May 11, 2017), ECF No. 23. The Federal Circuit rejected this argument, concluding that “the facts indicate that there was no action Supernus could have taken to advance prosecution of the patent.” *Supernus*, 913 F.3d at 1360. So too here.

As in *Supernus*, the PTO argues that Lundbeck could have availed itself of the eight-month safe harbor under Rule 1.704(c)(13) and removed the shading from the tables during this period. *See* Def.’s Resp. Br., *passim* (Dkt. 35). But that ignores the fact that Lundbeck was not on notice there was a shading issue to fix. The PTO does not point to *any* evidence or finding in the Administrative Record that the shading in Lundbeck’s tables rendered the text within them illegible. *SUF* ¶¶ 3–5, 8–9. Nor does the PTO point to any evidence or finding in the Administrative Record that Lundbeck should have known that the perfectly legible tables it filed with very light gray shading would somehow be reproduced in a manner that would cause legibility problems for the PTO. *See id.* This is because no such evidence exists. Recognizing that the regulations the PTO actually cited and relied upon to justify its patent term adjustment decision say nothing about shading, the PTO attempts to import a public announcement from the MPEP about the *potential* perils of gray shading that are not applicable to *this case*. If the PTO wanted to ban all gray shading, it could easily do so. To-date, it *still* has not. *See* *SUF* ¶ 9.

As was the case in *Supernus*, the PTO fails to identify any reasonable efforts Lundbeck could have taken to discover the legibility issue, if any even existed, *see infra* at 28–35. Lundbeck could no more fix an issue of which it was not aware than Supernus could file an IDS notifying the PTO of a foreign opposition that did not yet exist. *Compare* *SUF* ¶¶ 5, 30–31, with *Supernus*, 913 F.3d at 1360. Having filed an entirely legible national stage application,

Lundbeck reasonably waited for the PTO to process it. Section 154(b)(2)(C)(i) does not allow the PTO to deduct patent term during the period where Lundbeck acted reasonably. *See Supernus*, 913 F.3d at 1360–61. The PTO’s assessment of 55 days of Applicant Delay for the period after January 17, 2020 and through March 11, 2020 was *ultra vires*. *See id.*

3. Lundbeck responded to the formalities notice within three months, which 35 U.S.C. § 154(b)(2)(C)(ii) says is reasonable *per se*.

The parties do not dispute that Lundbeck responded to the PTO’s March 11, 2020 Formalities Notice within three months, as instructed by the PTO. *See* SUF ¶¶ 10, 13. Nevertheless, the PTO takes the remarkable position that it is free to count “response time to Office actions (and the like) against the applicant” for purposes of excusing its A Delay, even if the applicant fixes any formalities issue within the time specified both by the PTO and 35 U.S.C. § 154(b)(2)(C)(ii). Def.’s Resp. Br. at 27 (Dkt. 35). This makes no sense.

The PTO does not dispute that Congress provided guidance for how quickly an applicant should respond to a notification from the PTO in 35 U.S.C. § 154(b)(2)(C)(ii). *See* Def.’s Resp. Br. at 27 (Dkt. 35); *see also Supernus*, 913 F.3d at 1353 (“[a]n applicant is deemed to have failed to engage in reasonable efforts for the cumulative time *in excess of three months* that the applicant takes to respond to a notice of rejection, objection, argument, or other request from the USPTO”) (emphasis added). Nevertheless, because subsection (C)(ii) applies to B Delay and not A Delay, the PTO argues it can deduct the entirety of the response period, even though Lundbeck responded within three months *as instructed by the PTO*. SUF ¶¶ 10, 13. This is *ultra vires*.

Subsection (C)(iii) only allows the PTO to promulgate regulations specifying the “circumstances” where an applicant fails to engage in “reasonable efforts” to conclude prosecution. Lundbeck is not aware of *any* regulation specifying as a circumstance failure to respond to a formalities notice instantaneously, nor has the PTO identified any. In light of

Congress’s statement that it is reasonable to respond to an office action within three months in the case of B Delay, and in the absence of any rule or regulation adopting a different period for A Delay and justifying such a departure, the PTO’s position is arbitrary, capricious, and contrary to the statute. Indeed, it is contrary to the *PTO*’s position when promulgating Rule 1.704(c)(13). *See Patent Law Treaty Changes*, 78 Fed. Reg. at 62384 (stating the three-month period under subsection (C)(ii) applies to pre-examination formalities notices). The PTO offers no reason why an applicant has failed to engage in reasonable efforts if it fails to instantaneously respond to a formalities notice—or any other document before the PTO provides its first office action—when Congress has indicated that it is perfectly reasonable to respond within three months.

The PTO’s cheeky response that any “‘manifestly unfair’ PTA results” from its decision to require instantaneous responses to formalities notices “is a problem for Congress to solve” misses the mark. Def.’s Resp. Br. at 27 (Dkt. 35). Congress *already* solved this problem and indicated through the structure of 35 U.S.C. § 154(b)(2)(C) that responding to the PTO within three months is *per se* “reasonable.” *See Timex*, 157 F.3d at 882; *Gilead*, 778 F.3d at 1348. At minimum, if the PTO wanted to apply a different rule for A Delay, it would need to give clear notice (through rulemaking) of that and explain the reasons for that difference. It has done neither. Accordingly, Lundbeck cannot be charged with the 86 days of Applicant Delay for the period from March 11, 2020 to June 5, 2020.

B. MPEP § 608.01(I) Does Not Justify the PTO’s Decision.

1. The PTO Never Cited Or Relied On MPEP § 608.01(I). To Do So Now Is An Impermissible *Post Hoc* Rationalization.

The PTO scolds Lundbeck for failing to address MPEP § 608.01(I) in its briefing—while failing to mention that the PTO *never once cited MPEP § 608.01(I) until now*. *See* SUF ¶¶ 46–52. That is, the PTO did not cite or rely on MPEP § 608.01(I) when issuing the March 11, 2020

Formalities Letter. *See* SUF ¶ 45. Instead, the PTO relied on the plain language of its promulgated regulations under Title 37 and PCT Rule 11:

(The application is) not in compliance with 37 CFR 1.52 and PCT Rule 11 because pages 80-84, AND 139 CONTAIN(S) SHADING IN THE TABLE(S). Application papers (including any electronically submitted papers) must be presented in a form having sufficient clarity and contrast between the background of the paper and the writing thereon to permit the Office to electronically reproduce the papers by use of digital imaging and optical character recognition. *See* 37 CFR 1.52(a)(1)(v) and PCT Rules 11.2(a) and 11.9(d).

SUF ¶ 7. The PTO also neither cited nor relied on MPEP § 608.01(I) in its February 7, 2022 Redetermination of Patent Term Adjustment, its April 13, 2022 Second Redetermination of Patent Adjustment, or its February 24, 2023 Decision Denying Request for Redetermination of Patent Term Adjustment. *See* SUF ¶¶ 23–24, 29–32, 48–50. It never cited or relied on MPEP § 608.01(I) *at all*.¹⁰ *See* SUF ¶ 52.

As the PTO did not cite or rely on MPEP § 608.01(I) in the Administrative Record, to do so now is an impermissible *post hoc* rationalization. *See Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020) (rejecting belated, new arguments as “impermissible *post hoc* rationalizations” that were “not properly before” the court). Accordingly, Lundbeck did not “conveniently omit[]” MPEP § 608.01(I) from the record. *See* Def.’s Resp. Br. at 6 (Dkt. 35). MPEP § 608.01(I) is not *in* the Administrative Record, played no role in the PTO’s decision, and may not be used to justify the PTO’s decision now. *See In re Sang Su Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002) (“courts may not accept appellate counsel’s *post hoc* rationalization for agency action ... review of an administrative decision must be made on the grounds relied upon by the agency” (citation and markings omitted)).

2. The PTO Waived Application Of *Chevron* Deference And, In Any Event,

¹⁰ The PTO also did not rely on the other publication cited in its Responsive Brief. *See* SUF ¶ 53.

The MPEP Is Not Entitled To Any.

As mentioned *supra*, the PTO waived any argument that “its conduct is entitled to deference under *Chevron*.” Def.’s Resp. Br. at 15 n.7 (Dkt. 35). But even if it had not included such a waiver, the MPEP “does not have the force of law or the force of the rules in Title 37 of the Code of Federal Regulations.” *See supra* at 4. It is not entitled to *Chevron* deference.

Chevron deference for an agency’s regulation is appropriate only when the regulation was promulgated using notice-and-comment procedures. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016) (holding that “*Chevron* deference is not warranted where the regulation is ‘procedurally defective’—that is, where the agency errs by failing to follow the correct procedures in issuing the regulation”); *see also Nat’l Org. of Veterans’ Advocates, Inc. v. Sec’y of Veterans Affairs*, 260 F.3d 1365, 1381 (Fed. Cir. 2001) (if agency desired “its interpretation of statutes to be afforded *Chevron* deference, its regulations should be promulgated using notice-and-comment procedures”); *Butterbaugh v. DOJ*, 336 F.3d 1332, 1340–41 (Fed. Cir. 2003) (“agency personnel policies embodied in informal sources such as handbooks and directives ... do not ordinarily merit *Chevron* deference”). By contrast, *Chevron* deference is not warranted where the regulation is “not accompanied by any indication that it is the considered policy of the agency—[that] is not the sort of interpretation that Congress intended to carry the ‘force of law.’” *Caribbean Ispat Ltd. v. United States*, 450 F.3d 1336, 1340 (Fed. Cir. 2006). The MPEP was not promulgated using notice-and-comment procedures. Moreover, by the PTO’s own account, it does not and is not intended to “have the force of law.” Thus, the MPEP is not entitled to *Chevron* deference.

Further, courts have consistently held that regulations without the force of law cannot be given “controlling weight” in construing statutes or regulations promulgated through notice and comment. *See, e.g., Encino* at 224; *Eldredge v. DOI*, 451 F.3d 1337, 1342 (Fed. Cir. 2006)

(advisory opinion not entitled to *Chevron* deference because it was advisory and lacked the force of law). And the PTO makes no argument that Rule 1.704(c)(13) is ambiguous, requiring *Auer* deference to MPEP § 608.01(I)'s purported interpretation.¹¹ Cf. Def.'s Resp. Br. at 16.

The PTO's efforts to raise the MPEP to the status of a rule promulgated through notice and comment are thus foreclosed by ample precedent. The MPEP does not contain rules promulgated through notice and comment: it contains guidance. As such, not only can the MPEP forbid nothing—shading included—it cannot be the deciding factor in the construction of a statute. Yet, in its brief, the PTO argues for the first time at summary judgment that MPEP § 608.01(I) essentially controls both its interpretation of both 35 U.S.C. § 154(b)(2)(C)(i) and 37 C.F.R. § 1.704(c)(13). Precedent forbids this result.

In other words, the purpose of the MPEP is to serve as a resource for examiners and applicants. It is not intended to “bind the public in any way.” See MPEP Foreword. Thus, if the PTO itself concedes both in its Motion and in the MPEP that the MPEP “does not have the force of law,” it is improper and inaccurate to characterize MPEP § 608.01(I) as *prohibiting* gray shading or anything else. If the PTO wanted to prohibit shading of any kind in patent applications, it would need to promulgate a rule pursuant to the Administrative Procedure Act rulemaking process. The PTO's effort to bootstrap MPEP guidance into a rule with the force of law must fail.

II. THE PTO ABUSED ITS DISCRETION BY APPLYING RULE 1.704(C)(13) TO REDUCE LUNDBECK'S PATENT TERM.

¹¹ Any such argument is now forfeited. See *Tetra Tech AMT v. United States*, 128 Fed. Cl. 169, 184 (2016) (stating that it is “established that arguments not raised in the opening brief are waived”); see also *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006) (same); *Yaskowsky v. Phantom Eagle, LLC*, No. 4:19CV9, 2020 WL 809378, at *5 (E.D. Va. Feb. 18, 2020) (dismissing arguments not raised in the opening brief as untimely).

Because the PTO denies entitlement to *Chevron* deference for its decision, this case turns on the plain language of Section 154(b)(2)(C)(i) and structure of Section 154(b). *See* Def.’s Resp. Br. at 15 n.7. Accordingly, Lundbeck need not show that the PTO abused its discretion—it denies having any. *See id.* Regardless, even if the PTO claimed to benefit from deferential review of its interpretation of 35 U.S.C. § 154(b)(2)(C)(i), it abused that discretion.

A. Substantial Evidence Does Not Support The PTO’s Decision on Shading.

The PTO makes the remarkable assertion that Lundbeck “agreed with the [March 11, 2020] Formalities Letter.” Def.’s Resp. Br. at 26 (Dkt. 35). Nothing could be further from the truth. Lundbeck did *not* agree with the Formalities Letter. *See* SUF ¶¶ 3–9. Lundbeck chose not to delay prosecution by fighting a simple change the PTO wanted, even if unnecessary under the PTO’s own regulations. *See* SUF ¶ 13. Such a change was unnecessary because the tables that Lundbeck filed were *legible*. *See* SUF ¶¶ 3–9.

Rule 1.52(a)(1)(v) requires “sufficient clarity and contrast between the paper and the writing thereon to permit the direct reproduction of readily legible copies.” Lundbeck’s tables more than met this standard. *See* SUF ¶ 4. Even with the light gray shading, the text is clear, and the contrast between it and the shading is strong enough to make legible duplicates, as evidenced by the screenshots (or, to use another word, “reproductions”) included in this brief. *See* SUF ¶ 3. The PTO included no evidence whatsoever supporting any assertion that reproduction would somehow transform the text from legible to illegible. *See* SUF ¶ 8.

B. The PTO’s Unreasonable Interpretation of 35 U.S.C. § 154(b)(2)(C)(i) In Other Cases Does Not Justify Its Decision Here.

The PTO’s decision to deduct patent term from Lundbeck’s ’047 application, especially when contrasted to its actions with respect to the ’625 application, *see* SUF ¶¶ 37–44, was unreasonable. To rebut Lundbeck’s argument that the PTO inconsistently determines PTA, the

PTO argues that it “consistently and routinely” directs applicants to fix “shading problems.” *See* Def.’s Resp. Br. at 17 (Dkt. 35). This is a *non sequitur*.

Lundbeck does not challenge the PTO’s ability to identify legibility issues posed by its reproduction equipment. Indeed, as Lundbeck has repeatedly stated, *only* the PTO knows whether the particular shades of gray employed in a particular application will cause reproduction issues such that an application runs afoul of Rule 1.52(a)(1)(v). *See supra* at 13–23. That the PTO has informed other applicants of purported shading problems proves nothing. The question is whether the PTO has then attempted to blame those applicants for *the PTO’s own delays* in processing their applications and identifying these legibility issues, as the PTO attempts to do here. To that question, only a few of the examples presented by the PTO offer insight.

Exhibits F, G and H did not have relevant patent term adjustment calculations *at all*. Exhibit F was abandoned. *See* Dkt. 35-1 at US-0878-79 (Exhibit F) (notice of abandonment). No patent term adjustment is calculated for an abandoned application. For Exhibits G and H, the PTO informed the applicants of the purported legibility issue well within the eight-month period set by Rule 1.704(c)(13), enabling them to correct any issue before the deadline.¹² *See* Def.’s Resp. Br. at 18 (Dkt. 35) (noting the PTO provided a formalities notice for Exhibit G within two months of filing and within six months for Exhibit H). These applications tell us nothing of the PTO’s consistency when interpreting Rule 1.704(c)(13) in circumstances where the PTO does not inform the applicant of any legibility issue until long *after* the eight-month deadline set by Rule 1.704(c)(13) has expired. As for Exhibit E, on September 18, 2023, roughly a few weeks

¹² The PTO also provided the applicant in Exhibit F notice within the eight-month period under Rule 1.704(c)(13). Dkt. 35-1, Ex. F at US-856-857. Also, it is worth noting that Exhibit H received a notice of allowance in January 2024 and patent term adjustment has not yet been calculated. *See* Ex. 1 (notice of allowance).

after this lawsuit was filed, the PTO appears to have decided to deduct patent term on account of a shading issue. *See* Dkt. 35-1 at US-0833-0839 (Exhibit E). That decision is non-final and may still be challenged by the applicant. *See id.* Accordingly, it also tells us little about the PTO’s final interpretations of Rule 1.704(c)(13). The only useful information from these applications is that, like the formalities rejection at issue here, the PTO never cited or relied on MPEP § 608.01(I). *See* Dkt. 35 at US-0481 (Exhibit E) (citing Rule 1.52 and PCT Rule 11); *id.* at US-0856 (Exhibit F) (same); *id.* at US-0926 (Exhibit G) (same); *id.* at US-0937 (Exhibit H) (same).

This leaves Exhibits A, B, C, and D. In each of these examples, the PTO provided notice of a legibility issue long after the eight-month period under Rule 1.704(c)(13) had expired. *See* Def.’s Resp. Br. (Dkt. 35) at 17-18 (Exhibit A was sent a formalities letter 13 months after initial application; Exhibit B was sent a formalities letter 9 months after initial application; Exhibit C was sent a formalities letter 27 months after initial application; and Exhibit D was sent a formalities letter 32 months after initial application).¹³ The applicants in Exhibits A and B did not challenge the PTO’s decision to deduct patent term on account of a legibility issue for which the PTO delayed providing notice. *See* Ex. 2 (Exhibit A History); Ex. 3 (Exhibit B History). As for the applicants in Exhibits C and D, the PTO rebuffed their petitions to adjust the patent term with nearly identical language to that deployed in this case. *Compare* Ex. 4 (Exhibit C Decision), *and* Ex. 5 (Exhibit D Decision), *with* SUF ¶¶ 29–32. When contrasted to the PTO’s reasoning in the ’625 application, *see* SUF ¶¶ 37–44, these examples further illustrate the PTO’s “differential treatment” of similar cases without providing any explanation as to why applicants

¹³ Notably, as is true for Exhibits E through H, the formalities notices for Exhibits A through D also did not mention MPEP § 608.01(I). *See* Dkt. 35 at US-0018 (Exhibit A) (citing Rule 1.52 and PCT Rule 11); *id.* at US-0043 (Exhibit B) (same); *id.* at US-0060 (Exhibit C) (same); *id.* at US-0106 (Exhibit D) (same).

must rely on the luck of the draw as to when they receive a formalities letter or which patent examiner will handle their petition to correct any deduction of patent term. *See U.S. Postal Serv. v. Postal Regulatory Comm’n*, 785 F.3d 740, 753 (D.C. Cir. 2015) (“we owe no deference to an agency determination that is largely incomprehensible” (internal markings omitted)).

The PTO argues that its discrepancy in alerting applicants of shading issues is irrelevant. *See* Def.’s Resp. Br. (Dkt. No. 35) at 25 (noting that there is no statutory or regulatory obligation to send a Formalities Letter by a certain time). This ignores 35 U.S.C. § 154(b)(1)(A)(i). *See supra* at 9–13. Other than its specious argument that there is no statutory deadline, the PTO fails to explain *why* it sends some formalities letters before the eight-month deadline and why it sends others after—sometimes more than *two-years* after—the eight-month deadline. *See U.S. Postal Serv.*, 785 F.3d at 753 (“an agency’s exercise of its statutory authority [must] be reasonable and reasonably explained.”) (quoting *Mfrs. Ry. Co. v. Surface Transp. Bd.*, 676 F.3d 1094, 1096 (D.C. Cir. 2012)); *LePage’s 2000, Inc. v. Postal Regulatory Comm’n*, 642 F.3d 225, 232 (D.C. Cir. 2011) (“differential treatment of seemingly like cases” is unreasonable). Remarkably, when promulgating Rule 1.704(c)(13), the PTO said the pre-examination process should be completed within five months. *See* Patent Law Treaty Changes, 78 Fed. Reg. at 62384.

Indeed, the unreasonable, arbitrary and capricious nature of the PTO’s application of Rule 1.704(c)(13) is further illustrated by another patent application: U.S. Application No. 14/919,594 (the “’594 application”).¹⁴ There, on October 21, 2015, the applicant filed a

¹⁴ Having introduced Exhibits A through H into this case through its briefing, the PTO can hardly claim prejudice, forfeiture, or waiver with respect to the ’594 application. *Cf.* Def.’s Resp. Br. at 17–22. In *Sims v. Apfel*, the Supreme Court explained that issue waiver in administrative law is analogous to issue waiver in appellate proceedings, therefore “the desirability of a court imposing a requirement of issue exhaustion depends on the degree to which the analogy to normal adversarial litigation applies in a particular administrative

specification that included shading in several tables, as shown in the screenshots below. *See* Ex. 6 (the '594 specification).

Mechanical	RF = 0	RF = 1	RF = 2	RF = 3
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Figure 11. Shading on Page 63 of the '594 Application Specification

# of circuits	0	4	10	6
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Figure 12. Shading on Page 65 of the '594 Application Specification

Mechanical	RF = 0	RF = 1	RF = 2	RF = 3
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Figure 13. Additional Shading on Page 65 of the '594 Application Specification

proceeding.” 530 U.S. 103, 108-09 (2000). When “an administrative proceeding is not adversarial, ... the reasons for a court to require issue exhaustion are much weaker.” *Id.* at 110. Here, issue waiver does not apply because there were no adversarial proceedings. *See, e.g., Choat v. Rome Indus., Inc.*, 462 F. Supp. 728, 732 (N.D. Ga. 1978) (noting patent prosecution is an “ex parte proceeding[,]” not an adversarial one). Such proceedings are akin to Pension Benefit Guarantee Corporation’s (PBGC) determination of pension eligibility, which the D.C. District Court concluded was “inquisitorial” and therefore issue waiver did not apply. *See Furfari v. Pension Benefit Guar. Corp.*, No. CV 20-2424 (CKK), 2021 WL 2949169, at *6 (D.D.C. July 14, 2021) (noting that PBGC proceedings did not include an adversarial hearing, but rather an appeal that did not require briefing). Consequently, the Court allowed claimant’s new arguments because to do so otherwise would have “required [claimant] to intuit reasoning that was not stated in the agency action.” *Id.* at *7. To waive Lundbeck’s arguments here would be similarly unfair.

The PTO also makes the vague argument that Lundbeck waived unspecified arguments. *See* Def.’s Resp. Br. at 19 (Dkt. 35) (instructing the Court to compare the Administrative Record with Lundbeck’s Opening Brief without specifying exactly what arguments the PTO contends that Lundbeck waived). This is improper. “Courts are entitled to assistance from counsel, and an invitation to search without guidance is no more useful than a litigant’s request to a district court at the summary judgment stage to paw through the assembled discovery material.” *Olaplex, Inc. v. L’Oréal USA, Inc.*, 855 F. App’x 701, 712 (Fed. Cir. 2021) (quoting *Albrechtsen v. Bd. of Regents of Univ. of Wisc. Sys.*, 309 F.3d 433, 436 (7th Cir. 2002)). “Judges are not like pigs, hunting for truffles buried in the record.” *Id.* (quoting *Albrechtsen*, 309 F.3d at 436). Undeveloped arguments, like this one, are forfeited. *See SmithKline Beecham Corp.*, 439 F.3d at 1320.

Circuit Function	Circuit #	# Flex	Power	Sensor Cntrl	Sensor
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Figure 14. Shading on Page 82 of the '594 Application Specification

Circuit Function	Circuit #	!!! Level	# of Flex Connects	Unregulated Power	Regulated Power	Signal Distribution
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Figure 15. Shading on Page 92 of the '594 Application Specification

The PTO did not issue a formalities notice regarding this shading before providing an office action. *See* Ex. 7 ('594 Application History). Instead, on August 22, 2017, the PTO issued a restriction/election requirement. *See* Ex. 8 (Aug. 22, 2017 Restriction/Election Requirement). Because this office action came well after the 14-month deadline set by 35 U.S.C. § 154(b)(1)(A)(i), the applicant was entitled to 244 days of A Delay. *See* Ex. 9 ('594 Patent Term Adjustment Calculations). Only *after* the PTO issued a notice of allowance did the PTO identify the purported shading issue. *See* Ex. 10 (Jun. 29, 2018 Notice to File Corrected Application Papers). Because this notice happened to come *after* the PTO issued its first office action, the applicant was not charged with *any* Applicant Delay for the shading issue. *See* Ex. 9 ('594 Patent Term Adjustment Calculations). This further demonstrates the arbitrary and capricious nature of the PTO's interpretation of Rule 1.704(c)(13).

The PTO's position amounts to the following: An applicant might be charged with Applicant Delay for shading if (1) the PTO happens to not issue a formalities notice until after the eight-month deadline has passed, as happened in this case and PTO Exhibits A through D; (2) the PTO declines to accept responsibility for its delay in issuing a formalities notice, as it did in the '625 application, *see* SUF ¶¶ 37–44, or (3) the PTO decides to issue a formalities notice *before* its first office action instead of *after* its first office action, as it did in the '594 application. When combined with the PTO's unexplained decision to blame applicants for certain deficiencies and not others, *see* Pl.'s Opening Br. at 28–29 (Dkt. 29), the PTO's interpretation of

35 U.S.C. § 154(b)(2)(C)(i) is arbitrary and capricious, and the unreasonableness is evident from the examples provided *by the PTO*.

Each of the applicants in the examples provided by the PTO corrected the shading issue within three months of the PTO's formalities notice. *See* Def.'s Resp. Br. at 17–18 (Dkt. 35) (Exhibit A applicant corrected within two months; Exhibit B applicant corrected within two months; Exhibit C applicant corrected within one month; Exhibit D applicant corrected within two months; Exhibit E applicant corrected within two months; Exhibit F applicant corrected within two months; Exhibit G applicant corrected within one month; Exhibit H applicant corrected within two months). Under the PTO's interpretation of 35 U.S.C. § 154(b)(2)(C)(i), as *sometimes* applied through the application of Rule 1.704(c)(13), *cf.* SUF ¶¶ 37–44, no patent term could be deducted from the applicants in Exhibits F through H because the PTO *happened* to notify those applicants of the legibility issue within the first eight months of filing. But, even though the applicants in Exhibits A through E responded to the PTO's formalities notice in the *same timeframe*, the PTO's unreasonable interpretation of 35 U.S.C. § 154(b)(2)(C)(i) led it to deduct patent term from their applications.

These examples confirm that the PTO's application of Rule 1.704(c)(13) has nothing to do with the *applicant's conduct*. Instead, under the PTO's unreasonable, arbitrary, and capricious interpretation of 35 U.S.C. § 154(b)(2)(C)(i), an applicant's fate is left to the unpredictable and unexplained choices of the *PTO*. If the PTO processes the application quickly (as it did for Exhibits F, G, and H and said it could do when promulgating Rule 1.704(c)(13), *see* Patent Law Treaty Changes, 78 Fed. Reg. at 62384), then there will be no Applicant Delay. If the PTO processes the application *super slowly* (as it did for the '594 application where a purported shading issue was not identified until after a notice of allowance), then there will also

be no Applicant Delay. The only time Applicant Delay is accrued is if the PTO processes the application and identifies a shading defect after the eight-month deadline the PTO imposed under Rule 1.704(c)(13) but *before* issuing the first office action (or notice of allowance). An applicant's conduct in responding to the noticed defect is entirely absent from the equation. The only timing that matters is the *PTO's*. This is not a reasonable interpretation of Section 154(b)(2)(C)(i). *See Gilead*, 778 F.3d at 1348; *Supernus*, 913 F.3d at 1360. It is not even a reasonable interpretation of Rule 1.704(c)(13), which was meant to address the circumstance where an applicant did not file a specification or claims *at all*. *See Patent Law Treaty Changes*, 78 Fed. Reg. at 62384–85. When a specification was filed with the initial application, even the PTO said the entire pre-examination formalities review process should be completed within “five months.” *Id.* at 62384. The PTO's decision is *ultra vires* and must be set aside.

III. LUNDBECK IS ENTITLED TO JUDGMENT ON ITS TAKINGS CLAIM.

Lundbeck enjoys a substantial and cognizable property right in the full and complete term of the '822 patent. *See* 35 U.S.C. § 154; *see also Brulotte v. Thys Co.*, 379 U.S. 29, 30–31 (1964) (acknowledging property right to exclusivity during the patent term); *see also Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 (1945) (“that patent is property... has long been settled”). Hence, the PTO's decision is a taking without just compensation, in violation of the Fifth Amendment. To the extent the PTO addresses this argument, it does so in a footnote on the last page of its brief, stating only: “That claim rises and falls with the APA claim ... So here it falls.” Def's. Resp. Br. at 28 n.11 (Dkt. 35). For the reasons described *supra*, Lundbeck's APA claim should succeed. Accordingly, so should its takings claim.

CONCLUSION

For all these reasons, the Court should deny the PTO's motion for summary judgment, grant Lundbeck's motion, and restore the PTA for the '822 patent to 91 days.

Dated: February 27, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 27th day of February, 2024, the foregoing:

**PLAINTIFF H. LUNDBECK A/S'S COMBINED OPPOSITION TO DEFENDANT'S
CROSS MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF ITS
MOTION FOR SUMMARY JUDGMENT**

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